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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,999	12/22/2005	Marc Riemenschneider	RO0989US (#90568)	1652
7590 D Peter Hochberg Co The Baker Building-6th Floor 1940 East 6th Street Cleveland, OH 44114-2294		12/09/2008	EXAMINER LEWIS, KIM M	
			ART UNIT 3772	PAPER NUMBER
			MAIL DATE 12/09/2008	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/532,999	<b>Applicant(s)</b> RIEMENSCHNITTER, MARC
	<b>Examiner</b> Kim M. Lewis	<b>Art Unit</b> 3772

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on the rce filed 11/12/08.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-31 is/are pending in the application.

4a) Of the above claim(s) 18 is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-17 and 19-29 is/are rejected.

7) Claim(s) 30 and 31 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5) Notice of Informal Patent Application

6) Other: \_\_\_\_\_

**DETAILED ACTION**

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/08 has been entered.
2. As requested in the submission, claims 1-9,11-15 and 18 have been amended and claims 25-31 have been added. Applicant should note that the status identifier for claim 18 is incorrect since the claim is withdrawn. In response to the present office action, applicant is required to provide claim 18 with the correct status identifier.
3. Claims 1-31 are pending in the instant application.

***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-3, 6, 9-10, 13-21 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,375,963 ("Repka et al.").

As regards claims 1-3, 6, 9-10, 13-17, 19-21 and 29 Repka et al. disclose a bioadhesive hot-melt extruded film for topical and mucosal adhesive applications and drug delivery and process for preparation thereof. More specifically, Repka et al. disclose a hot-melt extruded film for the transdermal or mucosal administration of active substances, whose adhesive force develops after humidification (see column 5, lines 3-15). Also disclosed is a film for the treatment of wounds contains, *inter alia*, hydroxypropyl cellulose, polyvinyl pyrrolidone, carbomer and polycarbophil, can be connected to an overlaying adhesive patch (note example 4). Repka et al. also disclose in example 7, a vitamin E adhesive patch that guards against wrinkles and senile lentigo contains, *inter alia*, Gantrez MS-955, polycarbophil and hydroxypropyl cellulose. Also disclosed is that the bioadhesive film also contains organic acids such as tartaric acid (note claim 1 and example 7). Further disclosed are acrylic polymers (note claim 30). Applicant should note that a polyacrylate is a polymer of an ester or salt of acrylic acid. Thus, the disclosure of "water-swellable polymers derived from acrylic acid or a pharmaceutically acceptable salt thereof, such as polyacrylic acid polymers..." at col. 3, lines 31-33, read on the non-psa polyacrylates.

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 4-5, 7-8, 11-12, 22, 23, 25, 26 and 28 are rejected under 35 U.S.C.

103(a) as being unpatentable over Repka et al. in view of U.S. Patent No. 6,682,721

("Kim et al.").

As regards claim 4, 5, 7, 8, 11 and 12, 22, 23, 25 and 26, Repka et al. fail to teach the ingredients as outlined in claims 4, 5, 7, 8, 11, 12, 22, 23, 25 and 26. Kim et al., however, discloses patches for teeth whitening which substantially discloses applicant's claimed invention. More specifically, as can be read from claim 3 of Kim et al., a number of polymers can be used alone or in combination to produce moisture activated adhesives. The list comprises PVM/MA copolymers and polyvinyl alcohols. The examples show that combinations of, for example, Gantrez S-97 with polyvinyl pyrrolidone (example 6) or polyvinyl alcohol with polyvinyl pyrrolidone (example 1) have the desired adhesive force on a moist substrate.

Absent a critical teaching and/or a showing of unexpected results derived from applicant's claimed adhesive formulation, the examiner contends it would have been obvious to one having ordinary skill in the art to combine the polymers specified in Repka et al., through routine experimentation, in the claimed ranges, with the polymers specified in the list in the Kim publication for the production of an adhesive layer that has an improved adhesive force on moist surfaces.

Re. claim 28, note the rejection of claim 7 above.

9. Claims 24 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Repka et al. in view of U.S. Patent No. 3,322,703 ("Lindemann").

As regards claims 24 and 27, Repka teaches carboxymethyl cellulose at col. 3, lines 24-27 but fails to teach carboxylic acid in the adhesive composition. Lindemann, however, teaches that it is known to use an organic acid such as carboxylic acid in the preparation of remoistenable adhesive in order to accomplish the esterification process. Thus, it would have been obvious to one having ordinary skill in the art to substitute the acid used for esterification in Repka for the carboxylic acid (dicarboxylic acid) in disclosed in Lindemann depending upon which polymeric material is used.

#### ***Allowable Subject Matter***

10. Claims 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Response to Arguments***

11. Applicant's arguments filed 11/12/08 have been fully considered but they are not persuasive. Applicant primarily argues that Repka et al. fail to teach an adhesive composition which contains a film-forming polyacrylate. Applicant should note that the disclosed polyacrylates are **capable** of forming a film and are non-pressure sensitive adhesive components as admitted by applicant on page 13 of the response filed 11/12/08.

12. Applicant additionally argues with respect to Lindemann and Kim et al., that these references fail to make up the deficiencies of Repka et al., and concludes that the present claims are not rendered obvious. The examiner, however, disagrees. As stated in the 102 rejection above, Repka et al. discloses all of the features outlined by the examiner and is therefore not deficient. The deficiencies of Repka et al. are outlined in the obviousness rejections in view of Lindemann and Kim et al., and the examiner has presented motivation and/or a suggestion as to why one having ordinary skill in the art would combine the teachings of Repka et al. and Lindemann and Repka et al. and Kim et al. in order to arrive at applicant's invention. Thus, claims 1-17 and 19-29 are not allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-4796. The examiner can normally be reached on Wednesday to Friday, from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Patricia Bianco, can be reached on (571) 272-4940. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kim M. Lewis/  
Primary Examiner  
Art Unit 3772

Kml  
December 4, 2008